

K111004

MAY 29 2012

SECTION 5

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Applicant Information:

Owner Name: Hansen Medical, Inc.
Address: 800 East Middlefield Road
Mountain View, CA. 94043
Office: 650-404-5800

Contact Person: Hassan Labay
Phone Number: 650 404 2770
Facsimile Number: 650 404 2773

Date Prepared: December 21, 2011

Device Information:

Classification: Class II
Trade Name: Hansen Medical Magellan™ Robotic System, NorthStar™
Robotic Catheter and Accessory components
Common name: Steerable Catheter Control System
Classification name: System, Catheter Control, Steerable (21 CFR 870.1290/DXX)

Predicate Devices:

The Hansen Medical Magellan Robotic System, including the NorthStar Robotic Catheter, is substantially equivalent to:

- Terumo Pinnacle Destination System (K080415)
- Hansen Medical Sensei® X Catheter Control System and Artisan Control Catheter (K102168)

Device Description:

The Hansen Medical Magellan Robotic System and NorthStar Robotic Catheter and Accessory Components are designed to facilitate remote navigation to anatomical targets in the peripheral vasculature. Subsequent to navigation, the system provides a conduit for manual placement of therapeutic devices. The Magellan Robotic System's operating principles are similar to those of the Sensei X Robotic Catheter System. The fundamental concept of the robotic system is based on a master/slave control system that enables and visualizes positioning of a steerable catheter tip at a desired point inside the vasculature, while enabling a physician to remain seated and away from the x-ray radiation source.

A description of the Hansen System components (Magellan Robotic System, Magellan Robotic Catheter and Sterile Accessory Components) is provided below.

Magellan Robotic System

The major components of the Magellan Robotic System are (1) Workstation, (2) Remote Catheter Manipulator (RCM) with Remote Wire Manipulator (RWM), (3) Set-Up Joint (SUJ), Rail, and Bedside Electronics Module (BEM), (4) Bedside Pendant or Controller, and the (5) Electronics Rack.

Table 5-1: Description of Magellan Robotic System Components

Component	Description
Workstation	The Workstation provides the physician with a display for the fluoroscopic image and input devices for commanding the NorthStar Robotic Catheter and commercial guidewire remotely from the patient's bedside. The input devices include a touch-screen, a pendant controller housing command buttons, and a joystick 3D controller.
Remote Catheter Manipulator (RCM)	The RCM is a servo-actuator system that translates the physician's commands to insert and articulate the NorthStar Robotic Catheter.
Remote Wire Manipulator (RWM)	The RWM is a servo-actuator system that translates the physician's commands to insert and roll a 0.018 – 0.35" diameter guidewire. The RWM is mounted on the RCM and is considered part of the RCM.
Set-up Joint (SUJ) Rail	The SUJ is an articulated arm that supports and allows for positioning of the RCM during set-up, prior to the start of a procedure. The SUJ design is based upon the Sensei X SUJ modified to support the weight of the VCCS RCM with RWM. It is mounted to a custom rail system. The rail system is a table-mounted, lead screw actuated support for the SUJ.

Bedside Electronics Module (BEM)	The BEM contains the motor and encoder electronics.
Bedside Controller /Pendant	The Bedside Controller/Pendant is a second pendant controller located at the bedside, and has the same input command-buttons as the Workstation Controller. The physician may enter NorthStar Robotic Catheter commands at the patient's bedside while watching the bedside fluoroscopic image display.
Electronics Rack	The Electronics rack houses the computers, video frame-grabbers, and back-up power supply for the Magellan Robotic System.

NorthStar Robotic Catheter:

The NorthStar Robotic Catheter is a guiding catheter design to facilitate navigation to anatomical targets, placement of a guidewire, and manual delivery of therapeutic devices. It consists of a steerable inner Leader and a steerable outer Sheath. The NorthStar Robotic Catheter family consists of three different lengths of Leader and Sheath pairs. Both the Leader and Sheath are equipped with proximal hubs which enable them to be attached to the Magellan Robotic System for insertion, articulation and retraction.

Table 5-2: Description of Hansen Catheter Components

Component	Description
Leader	The Leader is a tubular catheter with four pull wires articulating the distal end. The Leader is compatible with 0.018 - 0.035" guidewires. The Leader has a 6F outer diameter and 3F inner diameter, and is available in three different lengths. The Leader fits inside the Sheath and is only used inside the Sheath.
Sheath	The Sheath is a tubular catheter with four pull wires articulating the distal end. The Sheath has a 9F outer diameter and 6F inner diameter. The Sheath is available in three different lengths. The Sheath fits around the Leader and may be used with or without the Leader.

Accessory Components

The Accessory Components are sterile and disposable components that maintain the sterile field between the non-sterile RCM and the sterile Hansen Medical NorthStar Robotic Catheter as well as provide a means for rotating and inserting the guidewire and keep the catheter sliding smoothly during operation.

Intended Use:

The Magellan Robotic System, NorthStar Robotic Catheter and Accessory components are intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

Technological Characteristics of the Device Compared to the Predicate Device:

The Magellan Robotic System's operating principles are nearly identical to those of the Sensei X Robotic Catheter System cleared under (K102168). The fundamental concept of the system is based on a master/slave control system that enables and visualizes positioning of a steerable catheter tip at a desired point inside the vasculature, while enabling a physician to remain seated and away from the x-ray radiation source. The Magellan Robotic System has similar basic function, control mechanism, system components, communication and software architecture to those of the Sensei X Robotic Catheter System. The NorthStar Robotic Catheter interfaces with the Remote Catheter Manipulator (RCM) via the same mechanism as the existing Artisan Control Catheter cleared under (K102168). The mechanisms by which the Magellan Robotic System RCM articulates the distal ends of the NorthStar Robotic Catheter are the same as those used in the Sensei X Robotic Catheter System RCM. Similar to the Sensei X Robotic Catheter System, while using the Magellan System, the physician sits at a workstation console equipped with a pendant interface. The physician inputs motion commands to the pendant in order to control the motion of the NorthStar Robotic Catheter and guidewire. The Magellan Robotic System translates the pendant inputs into actuation of the catheter via the RCM and motion of the guidewire via the Remote Wire Manipulator (RWM). Moreover, performance testing demonstrated that the products perform in a substantially equivalent manner to the Sensei Robotic Control System. Therefore, Hansen Medical considers the Magellan Robotic System and NorthStar Robotic Catheter to be substantially equivalent to the legally marketed predicate Sensei Control Catheter System and Artisan Control Catheter Model (K102168) because it has similar technological characteristics utilizing robotic manipulation.

The Hansen Medical Magellan Robotic System and the predicate Pinnacle Destination Peripheral Guiding Sheath (cleared K080415) have the same intended use and similar indications, technological characteristics and performance. The minor differences in wording for the intended use statements of the respective products do not alter the intended patient or clinical effect, and, therefore, the Hansen System is substantially equivalent with respect to intended use. In addition, the key technological difference between the products relate to the ability to remotely control the steerable NorthStar Robotic Catheter compared to manual control for the Pinnacle Destination Sheath. However, this difference does not present any new issues of safety or effectiveness. Moreover, performance testing demonstrates that the products perform in a substantially equivalent manner.

Summary of Studies:

All necessary preclinical and clinical testing was conducted to support a determination of substantial equivalence to the predicate devices.

Bench/Preclinical Testing

Verification and validation activities were performed to ensure that the Magellan Robotic System, NorthStar Robotic Catheter and Accessory Components fulfilled system requirements and to ensure that the product design conforms to the user needs and intended uses. The testing included:

• Visual and Dimensional Verification	• Biocompatibility Testing
• Tensile Testing	• Package Testing
• Articulation Force Testing	• Device Fatigue Testing
• Articulation Angle Testing	• Shipping/Distribution Testing
• Guidewire insertion force	• Sterility Testing
• Tracking in simulated anatomy	• Shelf Life and Life Cycle Testing
• Device Leak Testing	• Coating Particulate Testing
• Device Bending Stiffness Testing	• Device Evaluation in Porcine model
• System Verification Testing	• System Electrical (IEC) Testing
• Electromagnetic Test (EMC)	• Software Validation Test

All of the tests were successfully executed.

The collective results of the bench testing demonstrate that the Magellan Robotic System, NorthStar Robotic Catheter and Accessory Components meet the established specifications necessary for consistent performance for its intended use. In addition the testing demonstrates that the system does not raise new questions of safety or effectiveness when compared to the predicate devices.

Biocompatibility:

Biological evaluation was performed on NorthStar Robotic Catheter per ISO 10993-1 testing requirements and the FDA General Program Memorandum # G95-1. The NorthStar Robotic Catheter is categorized as external communicating devices in contact with circulating blood with limited contact (≤ 24 hrs).

Biocompatibility on the NorthStar Robotic Catheter included : Cytotoxicity, Sensitization, Maximization, Acute System Toxicity, Intracutaneous Reactivity/Irritation, Complement Activation, Thrombogenicity (dog), Material Mediated Pyrogenicity, Hemolysis, In Vitro Platelet Aggregation, , Prothrombin time

assay and Partial Thromboplastin time assay. All of the tests were successfully passed.

Please note that the Magellan Robotic System does not come into blood/tissue contact and therefore, no biocompatibility testing was performed.

Sterilization Validation:

The NorthStar Robotic Catheter is sterilized using Ethylene Oxide (EtO) sterilization process. The NorthStar Robotic Catheter Accessory Components (Kit and Caddy) are sterilized using gamma irradiation. The validated sterility assurance level (SAL) is 10^{-6} .

The Magellan Robotic System is supplied non-sterile.

Animal Study:

Two Good Laboratory Practices (GLP) animal studies (5 and 30-days) were performed to evaluate the efficacy and acute (and subacute) safety of peripheral artery cannulation and subsequent therapeutic device deployment when using the Magellan Robotic System.

The first 5-day survival study demonstrated that the system functionality and performance, as implemented, met the system design requirements in vivo. This study was conducted in accordance with Good Laboratory Practices (GLP) Regulations (21 CFR, part 58) and compared remote catheterization with the Magellan Robotic System and NorthStar Catheter to manual catheterization. This animal study demonstrated that the Hansen System can be successfully used to navigate within the peripheral vasculature in a safe and effective manner. This study demonstrated that the use of the Hansen System resulted in fewer and less severe vascular injuries as compared to the manual control.

The second 30-day survival study conducted in accordance with Good Laboratory Practices (GLP) Regulations (21 CFR, part 58), demonstrated that the system functionality and performance, as implemented, met the system design requirements in vivo. This study compared remote catheterization and treatment using the Magellan Robotic System and NorthStar Catheter to manual catheterization and treatment. This animal study demonstrated that the Hansen System can be successfully used to navigate within the peripheral vasculature and to subsequently be used as a conduit for the delivery of therapeutic devices in a safe and effective manner. This study also demonstrated that the use of the Hansen System resulted in fewer and less severe vascular injuries as compared to the manual control.

Clinical Study

A prospective, single center multi operator, non-randomized, single arm study of 20 procedures (15 enrolled subjects) utilizing Hansen Medical Magellan Robotic System and Hansen Medical NorthStar Robotic Catheter was conducted to evaluate the safety and ease of use for navigation, angiographic assessment, and treatment in the peripheral vasculature. The study results showed that robotic navigation was used to successfully cannulate 20 of 20 target vessels. There were no device related adverse events. Selective angiography of the target vessel was completed in 20 cases. In all cases, the Magellan Robotic System was able to remotely navigate a robotically deflectable catheter (NorthStar Robotic Catheter) and guide-wire into the target vessel. In all 20 cases the NorthStar Robotic Catheter was robotically navigated to the targeted lesion with the artery. All patients were free from access site complications at discharge (29.8 ± 6.6 hours) as evidenced by ultrasound imaging confirmation of the contralateral common femoral artery.

Conclusion:

The results of bench testing, animal testing, clinical testing and compliance with applicable standards (section 002) provide reasonable assurance that the system has been designed and tested to assure conformance to the requirements for its indications for use.

Hansen Medical considers the Magellan Robotic System and NorthStar Robotic Catheter to be substantially equivalent to the legally marketed predicate Sensei Control Catheter System and Artisan Control Catheter Model cleared under K102168 because it has similar technological characteristics utilizing robotic manipulation. Additionally, Hansen Medical's Magellan Robotic System has the same intended use and similar indications, technological characteristics and performance to the predicate Pinnacle Destination Guiding Sheath cleared under K080415. The minor differences in wording for the intended use statements of the respective products do not alter the intended patient or clinical effect and, therefore, the Hansen Medical System is substantially equivalent to currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Hansen Medical, Inc.
c/o Phyllis Elson
800 East Middlefield Road
Mountain View, CA 94043

MAY 29 2012

Re: K111004

Trade/Device Name: Hansen Medical Magellan™ Robotic System, NorthStar™ Robotic Catheter and Accessory Components
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable catheter control system
Regulatory Class: Class II
Product Code: DXX, DRA
Dated: February 03, 2012
Received: February 06, 2012

Dear Ms. Elson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

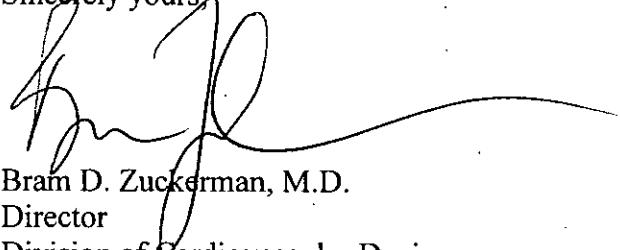
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Hansen Medical Vascular Catheter Control System
Hansen Catheter

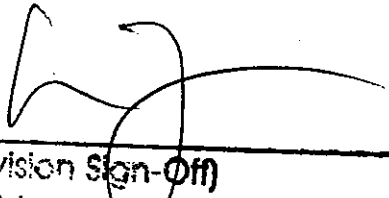
Indications for Use:

The Hansen Medical Vascular Catheter Control System, Hansen Catheter and accessory components are intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

Prescription Use x AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111 009